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Scientific Publication Bibliography Website

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Scientific publications and public presentations concerning the EHCSS

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Bibliographies

EHCSS Bibliography*

This EHCSS bibliography lists published or publicly presented scientific literature on or related to Philip Morris USA's Electrically Heated Cigarette Smoking System (EHCSS) as of the date listed on the homepage. The EHCSS Bibliography is meant to be comprehensive of the published or publicly presented scientific literature, but not all-inclusive.

Methods Bibliography*

This **Methods** bibliography lists selected published or publicly presented scientific guidelines, standards and methods that relate to the assessment of the Electrically Heated Cigarette Smoking System (EHCSS) as of the date listed on the homepage. The Methods Bibliography is not intended to be a comprehensive list of all published references available on the topic.

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Electrically Heated Cigarette Smoking System (EHCSS) Bibliography

This Electrically Heated Cigarette Smoking System (EHCSS) Bibliography lists published or publicly presented scientific literature on or related to Philip Morris USA's EHCSS as of the date listed on the homepage.

The EHCSS Bibliography is meant to be comprehensive of the published or publicly presented scientific literature, but not all-inclusive. Scientific articles related to EHCSS, including journal articles, reports (e.g. governmental reports), books or book chapters, publicly presented scientific materials, and issued utility patents related to the EHCSS are included in the bibliography.

Two generations of the EHCSS have been test-marketed to consumers under the trade name Accord® in the US and Oasis® in Japan. The **first generation** of EHCSS was first put on sale in Richmond, VA in August 1998, and in Osaka, Japan in January 1999. The **second generation** of EHCSS, which included modifications in cigarette and heater design, was introduced in Richmond in September 2002, and in the Japanese cities of Osaka, Kyoto, Kobe and Nara in April of the same year. Investigations from both generations add data to the overall assessment of potential toxicological significance of these products.

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References authored or co-authored by Philip Morris USA or Philip Morris USA affiliates' scientists are indicated with an asterisk (*).

References are listed in alphabetical order by first author, while patents are listed in numerical order.

The EHCSS bibliography is divided into 5 sections:

- I. Non-clinical studies
- II. Clinical studies
- III. Iron aluminide publications or presentations (Iron aluminide is an alloy developed for use in the heater blades of the EHCSS.)
- IV. US utility patents
- Reports from public health groups and background information including schematic of EHCSS

Some of these publications are in the "pdf" format. To view a "pdf" file, you must use Adobe Acrobat® Reader® (version 5.0 or above). This software is available from the Adobe website. To view details in the "pdf" documents, use the "zoom in tool" button found on the tool bar.

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Electrically Heated Cigarette Smoking System (EHCSS) Bibliography

[I. <u>Non-clinical studies</u>] [II. <u>Clinical studies</u>]
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[V. <u>Reports from public health groups and background information including schematic of EHCSS</u>]

I. Non-clinical studies

- Gerstenberg, B.; Stinn, W.; Reininghaus, W., "Comparison of environmental tobacco smoke from an electrically heated and a conventional cigarette". Program Booklet and Abstracts 54th Tobacco Science Research Conference 19; 2000. Poster presented at the 54th Tobacco Science Research Conference, Nashville, TN, September 24-27, 2000. The Toxicologist 60 (1-5): 431; 2001. Poster presented at the 40th Annual Meeting of the Society of Toxicology, San Francisco, CA, March 25-29, 2001. * Poster
- Lau, R.W.; Hirnikel, D.J.; Roethig, H.J., "Environmental tobacco smoke from smoking conventional and electrically heated cigarettes". Poster presented at the 2002 Annual Meeting of ISEA/ISEE, Vancouver, BC Canada, August 11-15, 2002. * Poster
- Roemer, E.; Meisgen, T.J.; Tewes, F.J.; Solana, R.P., "Discrimination of cigarette mainstream smoke condensates with the Salmonella reverse mutation assay". The Toxicologist 42 (1-S): 295; 1998. Poster presented at the 37th Annual Meeting of the Society of Toxicology, Seattle, WA, March 1-5, 1998. * Poster
- Roemer, E.; Vanscheeuwijck, P.; Elves, R.G.; Fournier, J.A., "Ammonlum magnesium phosphate in the paper wrapper of an electrically heated cigarette reduces the biological activity of the resulting smoke". *Toxicological Sciences* 66 (1-S): 26; 2002. Poster presented at the 41st Annual Meeting of the Society of Toxicology, Nashville, TN, March 17-21, 2002. (second generation) * Poster
- Rustemeier, K.; Patskan, G.; Haussmann, H.-J., "The influence of a modified puffing regimen on the yields of smoke constituents from electrically heated and conventional research cigarettes". *The Toxicologist* 54 (1): 16; 2000. Poster presented at the 39th Annual Meeting of the Society of Toxicology, Philadelphia, PA, March 19-23, 2000.
 Poster
- Stabbert, R.; Schaefer, K.-H.; Biefel, C.; Rustemeier, K., "Analysis of aromatic amines in cigarette smoke". Program Booklet and Abstracts 55th Tobacco Science Research Conference. 69; 2001. Verbal presentation at the 55th Tobacco Science Research Conference, Greensboro, NC, September 9-12, 2001. *
- Terpstra, P.M.; Reininghaus, W., "Chemical and biological evaluation of smoke from an electrically heated cigarette". Program and Abstracts of the 2nd Congress of Asian Society of Toxicology 151; 2000. Poster presented at the 2nd Congress of Asian Society of Toxicology, Cheju Island, Korea, August 23-25, 2000. * Poster
- Terpstra, P.M.; Reininghaus, W.; Solana, R.P., "Evaluation of an electrically heated clgarette". The Toxicologist 42 (1-S): 295; 1998. Poster presented at the 37th Annual Meeting of the Society of Toxicology, Seattle, WA, March 1-5, 1998. * Poster
- Tewes, F.J.; Veltel, D.J.; Heil, M.; Solana, R.P., "Discrimination of cigarette mainstream smoke with the neutral red uptake cytotoxicity assay". *The Toxicologist* 42 (1-S): 295; 1998. Poster presented at the 37th Annual Meeting of the Society of Toxicology, Seattle, WA, March 1-5, 1998. * Poster
- Voncken, P.; Gerstenberg, B.; Rustemeier, K.; Stabbert, R.; Patskan, G.; Haussmann, H.-J., "Chemical analysis of selected cigarette mainstream smoke constituents for comparative product integrity testing". Program Booklet and Abstracts 52nd Tobacco Science Research Conference 52: 36; 1998. Verbal presentation at the 52nd Tobacco Science Research Conference, Atlanta, GA, September 13-16, 1998. *
- Vanscheeuwijck, P.M.; Anskeit, E.A.; Teredesai, A.; Solana, R.P., "Equi-effect design for subchronic inhalation toxicity studies comparing conventional and novel cigarette prototypes". *The Toxicologist* 42 (1-S): 295, 1998. Poster presented at the 37th Annual Meeting of the Society of Toxicology, Seattle, WA, March 1-5, 1998. * Poster

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Electrically Heated Cigarette Smoking System (EHCSS) Bibliography

[I. Non-clinical studies] [II. Clinical studies]
[III. Iron aluminide publications or presentations] [IV. US utility patents]
[V. Reports from public health groups and background information including schematic of EHCSS]

II. Clinical studies

- Breland, A.; Buchhalter, A.; Evans, S.; Eissenberg, T., "Laboratory evaluation of the withdrawal suppression, physiological effects, carbon monoxide boost, and nicotine delivery of two novel smoking systems". Proceedings, 63rd Annual Scientific Meeting College on Problems of Drug Dependence S19 (paper 64), 2001. Presentation at the 63rd Annual Meeting of the College on Problems of Drug Dependence, Scottsdale, AZ, June 16-21, 2001.
- Breland, A.; Buchhalter, A.; Evans, S.; Eissenberg, T., "Comparison of the withdrawal suppression, physiological effects, and nicotine delivery of two novel smoking systems". Presentation at the 7th Annual Meeting of the Society for Research on Nicotine and Tobacco, Seattle, WA, March 23-25, 2001.
- Breland, A.B.; Buchhalter, A.R.; Evans, S.E.; Eissenberg, T., "Evaluating acute effects
 of potential reduced-exposure products for smokers: clinical laboratory methodology".

 Nicotine & Tobacco Research 4 (Suppl. 2) S131-S140; 2002.
- Buchhalter, A.R.; Elssenberg, T., "Preliminary evaluation of a novel smoking system: effects on subjective and physiological measures and on smoking behavior". Nicotine & Tobacco Research 2 (1): 39-43; 2000. <u>Abstract</u> (Accessed 2/5/03).
- Buchhalter, A.R.; Eissenberg, T., "Reduced CO boost produced in humans smoking a novel smoking system". Presentation at the Society for Research on Nicotine and Tobacco Annual Meeting, San Diego, CA, March 5-7, 1999.
- Buchhalter, A.R.; Schrinel, L.; Elssenberg, T., "Withdrawal-suppressing effects of a novel smoking system: comparison with own brand, not own brand, and de-nicotinized cigarettes". Nicotine & Tobacco Research 3 (2): 111-118; 2001. Abstract (Accessed 2/5/03).
- Keely, J.P.; Hughes, J.R.; Hirsch, J.S., "Effects of a cigarette substitute on ongoing smoking". Poster presented at the 7th Annual Meeting of the Society for Research on Nicotine and Tobacco, Seattle, WA, March 23-25, 2001.
- Roethig, H.J.; Kinser, R.; Nelson, B.L.; Lau, R.W., "Investigation of biomarker of exposure of adult smokers smoking electrically heated and conventional cigarettes". Society for Research on Nicotine and Tobacco 8th Annual Meeting. 2002 Rapid Communications Posters 14; 2002. Poster presented at the Society for Research on Nicotine and Tobacco Annual Meeting, Savannah, GA, February 20-23, 2002.
 * Poster
- Roethig, H.J.; Kinser, R.D.; Nelson, B.L.; Oey, J.; Wang, N., "Short term clinical exposure evaluation of conventional and electrically heated cigarettes". Poster presented at the American College of Clinical Pharmacology Annual Meeting, San Francisco, CA, September 21-23, 2002. * Poster
- Roethig, H.J.; Oey, J.; Nelson, B.L.; Walk, R.-A., "Dose-response investigations of carboxyhemoglobin of adult smokers smoking conventional and electrically heated cigareties". *Toxicological Sciences* 66 (1-S): 26-27; 2002. Poster presented at the 41st Annual Meeting of the Society of Toxicology, Nashville, TN, March 17-21, 2002.
- Roethig, H.J.; Oey, J.; Nelson, B.L.; Walk, R.-A., "Investigations of carboxyhemoglobin of adult smokers of conventional cigarettes and an electrically heated cigarette". Poster presented at the 29th Annual Meeting of the Japanese Society of Toxicology, Nagoya Congress Center, Japan, June 18-20, 2002. * Poster

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Electrically Heated Cigarette Smoking System (EHCSS) Bibliography

[I. Non-clinical studies] [II. Clinical studies]
[III. Iron aluminide publications or presentations] [IV. US utility patents]
[V. Reports from public health groups and background information including schematic of EHCSS]

III. Iron aluminide publications or presentations

- Deevi, S.C., "Powder processing of FeAI sheets by roll compaction". Intermetallics 8: 679-685; 2000, *
- Deevi, S.C.; Swindeman, R.W., "Yielding, hardening, and creep behavior of FeAl alloy". Materials Science and Engineering A258: 203-210; 1998. Presented at the International Symposium on Iron Aluminide: Alloy Design, Processing, Properties, and Applications, San Antonio, TX, February14-19, 1998.*
- Deevi, S.C.; Zhang, W.J.; Liu, C.T.; Reddy, B.V., "The development of a ductile and creep resistant TiAl-base alloy". MRS Fall Meeting, Boston, MA, November 27, 2000. Abstracts from the 2000 Fall Meeting, November 27 - December 1, 2000. * Abstract (Accessed 2/5/03). [Abstract available through the Materials Research Society, http://www.mrs.org/, page 2 abstract number N1-2. Copyright @MRS. All rights reserved.]
- Deevi, S.C.; Hajaligol, M.R.; Sikka, V.K., "Thermomechanical processing of plasma sprayed FeAI-based intermetallic sheets". Presented at the ASM Materials Solutions Conference and Exposition 2000, St. Louis, MO, October 9-10, 2000. *
- Hajaligol, M.R.; Deevi, S.C.; Sikka, V.K.; Scorey, C.R., "A thermomechanical process to make iron aluminide strip". *Materials Science and Engineering* A258: 249-257; 1998.
 Presented at the Power Metallurgy World Congress & Exhibitions, Granada, Spain, October 18 - 22, 1998 (#634) and at the International Symposium on Iron Aluminide: Alloy Design, Processing, Properties, and Applications, San Antonio, TX, February 14 -19, 1998. *
- Jaske, C.E.; Deevi, S.C. "Fatigue, and cyclic deformation behavior of iron aluminide", *Materials Science and Engineering* A258: 211-218; 1998. Presented at the International Symposium on Iron Aluminide: Alloy Design, Processing, Properties, and Applications, San Antonio, TX, February14 -19, 1998.*
- Jena, P.; Reddy, B.V.; Deevi, S.C.; Lilly, A.C., "Electronic structure and transport properties of Fe-Al alloys". Presented at the Intermetallics for the Third Millennium, Materials Park, OH, November 1, 1999.
- Lilly, A.C.; Deevl, S.C.; Gibbs, Z.P., "Electrical properties of iron aluminides". *Materials Science and Engineering* A258: 42-49; 1998. Presented at the International Symposium on Iron Aluminide: Alloy Design, Processing, Properties, and Applications, San Antonio, TX, February 14 -19, 1998. *
- Lilly, A.C.; Deevi, S.C.; Sikka, V.K.; Hajaligol, M.R.; Fleischhauer, G.S.; Scorey, C.R., "Development and production of FeAl-based intermetallic alloys". *Trans. Noferrous Met. Soc. China* 9: 309-317; 1999. Presented at the 3rd International Workshop on Ordered Intermetallic Alloys and Composites, Hangzhou, China, April 4-10, 1998. *
- Mistler, R.E.; Sikka, V.K.; Scorey, C.; McKemam, J.; Hajaligol, M., "Tape casting as a fabrication process for iron aluminide (FeAI) thin sheets". *Materials Science and Engineering* A258: 258-265; 1998. Presented at the International Symposium on Iron Aluminide: Alloy Design, Processing, Properties, and Applications, San Antonio, TX, February 14-19, 1998. *
- Rasouli, F.; Scorey, C.R.; McKernam, J.; Hajaligol, M.; Subbiah, M., "Tape casting of iron aluminide powders". Advances in Powder Metallurgy & Particulate Materials 9: 131-141; 2000. Presented at the 2000 International Conference on Powder Metallurgy & Particulate Materials, New York, May 30 to June 3, 2000.
- Reddy, B.V.; Deevi, S.C.; Lilly, A.C.; Jena, P., "Electronic structure of substoichiometric iron aluminide clusters". *Journal of Physics-Condensed Matter* 13 (36): 8363-8373; 2001. Presented at American Physical Society Meeting, Minneapolis, MN, March 21-24, 2000. * Abstract (Accessed 2/5/03).
- Strauss, J.T.; Scorey, C.R.; McKearn, J.; Hajaligol, M.R., "Polymer atomization of iron aluminide". *Materials Science and Engineering* A258: 291-297; 1998. Presented at the International Symposium on Iron Aluminide: Alloy Design, Processing, Properties, and Applications, San Antonio, TX, February 14 -19, 1998.
- Watkins, M.L.; Hinders, M.K., "The characterization of iron aluminide green sheet thermal properties". *Materials Science and Engineering* A258: 266-289; 1998. Presented at the Annual Meeting of the Minerals Metals Materials Society, San

15. Watkins, M.L.; Hinders, M.K.; Scorey, C.; Winfree, W., "The quantitative inspection of Iron aluminide green sheet using transient thermography". In: Green, R.E., Jr., ed. CP497, Nondestructive Characterization of Materials IX, New York: American institute of Physics; 1999; 361-368. Presented at the Ninth Annual Symposium on nondestructive characterization of materials, Sydney, Australia; June 28, 1999. *

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Electrically Heated Cigarette Smoking System (EHCSS) Bibliography

[l. Non-clinical studies] [li. Clinical studies]
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IV. US utility patents

(Patents may be viewed at the United States Patent and Trademark Office website.)

- US Patent No. 5,060,671. Counts, M.E., Laroy, B.C., Losee, D.B., Jr., Morgan, C.H., Smith, U., Sprinkel, F.M., Jr., and Utsch, F.V. "Flavor generating article". Issue date: October 29, 1991.
- US Patent No. 5,093,894. Deevi, S.C. and Sprinkel, F.M. "Efectrically-powered linear heating element". Issue date: March 3, 1992.
- US Patent No. 5,095,921. Losee, D.B., Morgan, C.H., Sprinkel, F.M., and Utsch, F.V. "Flavor generating article". Issue date: March 17, 1992.
- US Patent No. 5,144,962. Counts, M.E., Hajaligol, M.R., Morgan, C.H., Smith, U., Sprinkel, F.M., and Utsch, F.V. "Flavor-delivery article". Issue date: September 8, 1992
- US Patent No. 5,179,966. Losee, D.B., Morgan, C.H., Sprinkel, F.M., and Utsch, F.V. "Flavor generating article", Issue date: January 19, 1993.
- US Patent No. 5,224,498. Deevi, S.C. and Sprinkel, F.M. "Electrically-powered heating element". Issue date: July 6, 1993.
- US Patent No. 5,228,460. Grollimund, E.C. and Sprinkel, F.M. "Low mass radial array heater for electrical smoking article". Issue date: July 20, 1993.
- US Patent No. 5,249,586. Morgan, C.H. and Nichols, W.A. "Electrical smoking". Issue date: October 5, 1993.
- US Patent No. 5,261,424. Sprinkel, F.M., Jr. "Control device for flavor-generating article". Issue date: November 16, 1993.
- US Patent No. 5,269,327. Counts, M.E., Laroy, B.C., Losee, D.B., Jr., Morgan, C.H., Smith, U., Sprinkel, F.M., Jr., and Utsch, F.V. "Electrical smoking article". Issue date: December 14, 1993.
- US Patent No. 5,322,075. Deevi, S.C., Hajaligol, M.R., Herman, H., Higgins, C.T., Watkins, M.L., Waymack, B.E., and Yi, S. "Heater for an electric flavor-generating article". Issue date: June 21, 1994.
- US Patent No. 5,353,813. Deevi, S.C., Fleischhauer, G.S., and Keen, B.J., Jr.
 "Reinforced carbon heater with discrete heating zones", Issue date: October 11, 1994.
- US Patent No. 5,369,723. Counts, M.E. and Wrenn, S.E. "Tobacco flavor unit for electrical smoking article comprising fibrous mat". Issue date: November 29, 1994.
- US Patent No. 5,372,148. Higgins, C.T., Lucas, W.L., Sr., and McCafferty, H.J. "Method and apparatus for controlling the supply of energy to a heating load in an smoking article". Issue date: December 13, 1994.
- US Patent No. 5,388,594. Counts, M.E., Deevi, S.C., Fleischhauer, G.S., Hajaligol, M.R., Hayes, P.H., Higgins, C.T., Houck, W.G., Jr., Keen, B.J., Jr., Laroy, B.C., Lipowicz, P.J., Miser, D.E., Nichols, C.H., Stevens, W.H., Subbiah, M., Watkins, M.L., and Wrenn, S.E. "Electrical smoking system for delivering flavors and method for making same". Issue date: February 14, 1995.
- US Patent No. 5,408,574. Deevi, S.C. and Hajaligol, M.R. "Flat ceramic heater having discrete heating zones; in an electrically powered smoking article". Issue date: April 18, 1995.
- US Patent No. 5,468,936. Deevi, S.C., Hajaligol, M.R., Lleberman, P.D., Nichols, W.A., and Watkins, M.L. "Heater having a multiple-layer ceramic substrate and method of fabrication". Issue date: November 21, 1995.
- US Patent No. 5,479,948. Counts, M.E., Houck, W.G., Jr., Houghton, K.S., Lilly, A.C., Jr., Lipowlcz, P.J., Myracle, J.L., Sprinkel, F.M., Washington, J.M., and Wrenn, S.E. "Electrical smoking article having continuous tobacco flavor web and flavor cassette therefore". Issue date: January 2, 1996.
- 19. US Patent No. 5,480,025. Draucker, J.B., Hansen, C.D., Jr., Newsome, R.W., and

- rmain, A.w. arep-shaped inhermante for use with short digarettes and hinged itd box. Issue date: January 2, 1996.
- US Patent No. 5,498,850. Das, A. "Semiconductor electrical heater and method for making same". Issue date: March 12, 1996.
- US Patent No. 5,498,855. Deevi, S.C. and Lilly, A.C., Jr. "Electrically powered ceramic composite heater". Issue date: March 12, 1996.
- US Patent No. 5,499,636. Baggett, J.D., Jr., Clark, D.A., Cowling, P.C., Uhl, R.G., and Wrenn, S.E. "Cigarette for electrical smoking system; Automated manufacture of cigarettes". Issue date: March 19, 1996.
- US Patent No. 5,505,214. Collins, A.L., Counts, M.E., Fleischhauer, G.S., Houck, W.G., Jr., Keen, B.J., Jr., Losee, D.B., Jr., Nichols, C.H., Raymond, W.R., Sprinkel, F.M., Utsch, F.V., Watkins, M.L., and Wrenn, S.E. "Electrical smoking article and method for making same". Issue date: April 9, 1996.
- US Patent No. 5,530,225. Hajaligol, M.R. "Interdigitated cylindrical heater for use in an electrical smoking article". Issue date: June 25, 1996.
- US Patent No. 5,570,779. Draucker, J.B., Hansen, C.D., Jr., Newsome, R.W., and Pham, X.M. "Step-shaped innerframe for use with short cigarettes and hinged lid box". Issue date: November 5, 1996.
- US Patent No. 5,573,692. Das, A., Lipowicz, P.J., and Sweeney, W.R. "Platinum heater for electrical smoking article having ohmic contact". Issue date: November 12, 1996.
- US Patent No. 5,591,368. Counts, M.E., Fleischhauer, G.S., Hajaligot, M.R., Hayes, P.H., Morgan, C.H., Nichols, W.A., Sharpe, D.E., and Watkins, M.L. "Heater for use in an electrical smoking system". Issue date: January 7, 1997.
- US Patent No. 5,595,706. Deevi, S.C., Fleischhauer, G.S., Hajaligol, M.R., Lilly, A.C., Jr., and Sikka, V.K. "Aluminum containing iron-base alloys useful as electrical resistance heating elements". Issue date: January 21, 1997.
- US Patent No. 5,613,504. Collins, A.L., Counts, M.E., Das, A., Deevi, S.C., Fleischhauer, G.S., Higgins, C.T., Houck, W.G., Jr., Keen, B.J., Jr., Lee Robert E III, Lilly, A.C., Jr., Losee, D.B., Jr., McCafferty, H.J., Nichols, C.H., Raymond, W.R., Ripley, R.L., Ritt, R.R., Sr., Scott, G.R., Sprinkel, F.M., Utsch, F.V., Watkins, M.L., and Wrenn, S.E. "Flavor generating article and method for making same". Issue date: March 25, 1997.
- US Patent No. 5,613,505. Campbell, J.M., Fleischhauer, G.S., Higgins, C.T., Ripley, R.L., Sharpe, D.E., Watkins, M.L., and Wrenn, S.E. "Inductive heating systems for smoking articles". Issue date: March 25, 1997.
- US Patent No. 5,649,554. Das, A., Fleischhauer, G.S., Grollimund, E.C., Houck, W.G., Jr., Lipowicz, P.J., Smith, U., Sprinkel, F.M., Washington, J.M., and Wrenn, S.E. * "Electrical lighter with a rotatable tobacco supply". Issue date: July 22, 1997.
- US Patent No. 5,659,656. Das, A. "Semiconductor electrical heater and method for making same". Issue date: August 19, 1997.
- US Patent No. 5,665,262. Collins, A.L., Deevl, S.C., Fleischhauer, G.S., Gansert, R., V, Hajaligol, M.R., Hayes, P.H., Herman, H., Higgins, C.T., Keen, B.J., Jr., Laroy, B.C., and Lilly, A.C., Jr. "Tubular heater for use in an electrical smoking article". Issue date: September 9, 1997.
- US Patent No. 5,666,976. Adams, J.M., Braunshteyn, M.S., Counts, M.E., Dale, G.M., Harris, C.W., Jones, D.H., Keen, B.J., Jr., Sanderson, W.G., Smith, B.S., Stevenson, B.W., and Wrenn, S.E. "Cigarette and method of manufacturing cigarette for electrical smoking system". Issue date: September 16, 1997.
- US Patent No. 5,666,977. Higgins, C.T., Raymond, W.R., and Sprinkel, F.M. "Electrical smoking article using liquid tobacco flavor medium delivery system". Issue date: September 16, 1997.
- US Patent No. 5,692,291. Deevi, S.C., Hayes, P.H., Laroy, B.C., Miser, D.E., and Stevens, W.H. "Method of manufacturing an electrical heater; for use in a smoking system". Issue date: December 2, 1997.
- US Patent No. 5,692,525. Counts, M.E., Houck, W.G., Jr., Moore, M.A., Sanderson, W.G., Watkins, M.L., and Wrenn, S.E. "Cigarette for electrical smoking system". Issue date: December 2, 1997.
- US Patent No. 5,692,526. Adams, J.M., Counts, M.E., Fleischhauer, G.S., Houck, W.G., Jr., Houghton, K.S., Keen, B.J., Jr., Sanderson, W.G., and Wrenn, S.E. "Cigarette for electrical smoking system". Issue date: December 2, 1997.
- US Patent No. 5,708,258. Counts, M.E., Fleischhauer, G.S., Hajaligol, M.R., Hayes, P.H., Higgins, C.T., Houck, W.G., Jr., Laroy, B.C., Lipowicz, P.J., Nichols, C.H., Subbiah, M., and Watkins, M.L. "Electrical smoking system". Issue date: January 13, 1908.
- US Patent No. 5,726,421. Beane, T.P., Fleischhauer, G.S., Hayes, P.H., Higgins, C.T., Jones, R.E., Nelson, J.R., Jr., and Ripley, R.L. "Protective and cigarette ejection

- US Patent No. 5,730,158. Collins, A.L., Counts, M.E., Das, A., Deevi, S.C., Lilly, A.C., Jr., Losee, D.B., Jr., Utsch, F.V., and Walkins, M.L. "Heater element of an electrical smoking article and method for making same". Issue date: March 24, 1998.
- US Patent No. 5,743,251. Howell, T.M. and Sweeney, W.R. "Aerosol and a method and apparatus for generating an aerosol", Issue date: April 28, 1998.
- US Patent No. 5,750,964. Counts, M.E., Deevi, S., Fleischhauer, G.S., Hajaligol, M.R., Hayes, P.H., Higgins, C.T., Houck, W.G., Jr., Keen, B.J., Jr., Laroy, B.C., Lipowicz, P.J., Miser, D.E., Nichols, C.H., Stevens, W.H., Subblah, M., Watkins, M.L., and Wrenn, S.E. "Electrical heater of an electrical smoking system". Issue date: May 12, 1998.
- US Patent No. 5,816,263. Counts, M.E., Houck, W.G., Jr., Moore, M.A., Sanderson, W.G., Watkins, M.L., and Wrenn, S.E. "Cigarette for electrical smoking system". Issue date: October 6, 1998.
- 45. US Patent No. 5,865,185. Collins, A.L., Counts, M.E., Das, A., Deevi, S.C., Fleischhauer, G.S., Higgins, C.T., Houck, W.G., Jr., Keen, B.J., Jr., Lee Robert E III, Lilly, A.C., Jr., Losee, D.B., Jr., McCafferty, H.J., Nichots, C.H., Raymond, W.R., Ripley, R.L., Ritt, R.R., Sr., Scott, G.R., Sprinkel, F.M., Utsch, F.V., Watkins, M.L., and Wrenn, S.E. "Flavor generating article; smoking article". Issue date: February 2, 1999.
- 46. US Patent No. 5,878,752. Adams, J.M., Crowe, W.J., Fleischhauer, G.S., Fournier, J.A., Hajaligol, M.R., Houck, W.G., Jr., Losee, D.B., Morgan, C.H., Naworal, J.D., Nunnally, H.N., Paine, J.B., III, Raymond, W.R., Ripley, R.L., Seeman, J., I, Sprinkel, F.M., and Walkins, M.L. "Method and apparatus for using, cleaning, and maintaining electrical heat sources and lighters useful in smoking systems and other apparatuses". Issue date: March 9, 1999.
- US Patent No. 5,880,439. Deevi, S.C. and Lilly, A.C., Jr. "Functionally stepped, resistive ceramic". Issue date: March 9, 1999.
- US Patent No. 5,902,501. Butler, N.R., Cobier, P.J., Ely, D.J., Nunnally, H.N., Sharpe, D.E., and Watkins, M.L. "Lighter actuation system". Issue date: May 11, 1999.
- US Patent No. 5,915,387. Baggett, J.D., Jr., Clark, D.A., Counts, M.E., Cowfing, P.C., Houck, W.G., Jr., Moore, M.A., Sanderson, W.G., Uhl, R.G., Watkins, M.L., and Wrenn, S.E. "Cigarette for electrical smoking system". Issue date: June 29, 1999.
- US Patent No. 5,934,289, Hajaligol, M.R. and Watkins, M.L. "Electronic smoking system". Issue date: August 10, 1999.
- US Patent No. 5,954,979. Counts, M.E., Crowe, W.J., Felter, J.L., Fleischhauer, G.S., Hajaligol, M.R., Hayes, P.H., Houck, W.G., and Nunnally, H.N. "Heater fixture of an electrical smoking system". Issue date: September 21, 1999.
- US Patent No. 5,967,148. Harris, C.W., Nunnally, H.N., Ripley, R.L., Sano, M., and Smith, B.S. "Lighter actuation system". Issue date: October 19, 1999.
- US Patent No. 5,988,176. Baggett, J.D., Jr., Clark, D.A., Cowling, P.C., Uhl, R.G., and Wrenn, S.E. "Cigarette for electrical smoking system". Issue date: November 23, 1999.
- US Patent No. 6,013,915. Watkins, M. "Process control by transient thermography". Issue date: January 11, 2000.
- US Patent No. 6,040,560. Fleischhauer, G.S., Higgins, C.T., Losee, D.B., Nelson, J.R., Jr., Ripley, R.L., Sano, M., Sharpe, D.E., and Watkins, M.L. "Power controller and method of operating an electrical smoking system". Issue date: March 21, 2000.
- US Patent No. 6,053,176. Adams, J.M., Braunshteyn, M.S., Hajaligol, M.R., and Sanderson, W.G. "Heater and method for efficiently generating an aerosol from an indexing substrate". Issue date: April 25, 2000.
- 57. US Patent No. 6,116,247. Banyasz, J.L., Burton, A.T., Campbell, J.M., Chan, W.G., Counts, M.E., Crowe, W.J., Fournier, J.A., Hayes, P.H., Houck, W.G., Jr., Lee Robert E III, Losee, D.B., Paine, J.B., III, Ripley, R.L., and Thomas, C.E., Jr. "Cleaning unit for the heater fixture of a smoking device". Issue date: September 12, 2000.
- US Patent No. 6,119,700. Fleischhauer, G. and Stevenson, B. "Brush cleaning unit for the heater fixture of a smoking device". Issue date: September 19, 2000.
- US Patent No. 6,125,866. Nichols, W.A. and Sprinkel, F.M., Jr. "Pump cleaning unit for the heater fixture of a smoking device". Issue date: October 3, 2000.
- US Patent No. 6,289,898. Fournier, J.A. and Paine, J.B. "Smoking article wrapper with improved filler". Issue date: September 18, 2001.
- US Patent No. 6,349,728. Pham, X.M. "Portable cigarette smoking apparatus". Issue date: February 26, 2002.
- US Patent No. 6,418,938. Fleischhauer, G., Stevenson, B., Minagawa, S., and Counts, M.E. "Brush cleaning unit for the heater fixture of a smoking device". Issue date: July 16, 2002.
- 63. US Patent No. 6,446,426. Sweeney, W.R. and Lilly, Jr., A.C. "Miniature pulsed heat

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Electrically Heated Cigarette Smoking System (EHCSS) Bibliography

[I. <u>Non-clinical studies</u>] [II. <u>Clinical studies</u>]
[III. Iron <u>aluminide</u> publications or presentations] [IV. <u>US utility</u> patents]
[V. Reports from public health groups and background information including schematic of EHCSS]

V. Reports from public health groups and background information

- Britton, J.C.; Bates, C.; Channer, K.; Cuthbertson, L.; Godfrey, C.; Jarvis, M.; McNeill, A., Nicotine addiction in Britain. A report of the Tobacco Advisory Group of the Royal College of Physicians. Royal College of Physicians of London; 2000. Report (Accessed 2/5/03). [Available through the Royal College of Physicians website, http://www.rcplondon.ac.uk/.]
- Environews Forum, Anonymous. Article entitled: "Help Stopping Smoking". Environmental Health Perspectives 107: A186-A187; 1999.
- Herbert, R., "What's new in nicotine and tobacco research?" Nicotine & Tobacco Research 3/2: 97-99: 2001.
- 4. National Cancer Institute, "Risks associated with smoking cigarettes with tow machine-measured yields of tar and nlcotine". Smoking and Tobacco Control Monograph No. 13. Bethesda, MD: U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute, NIH Pub. No. 02-5074; 2001. Publication (Accessed 2/5/03). [Available from the National Cancer Institute website, http://cancercontrol.cancer.gov/.)
- Rickert, W.S. (Chair); Benowitz, N.L.; Debethizy, D.; Carchman, R.; Henningfield, J.E.; Hoffmann, D.; Jenkins, R.A.; Massey, S.; Pauly, J.; Shiffman, S.; Slade, J., "Canada's expert committee on cigarette toxicity reduction". Conference proceedings, Toronto, Ontario, Canada, September 20-22, 1998. Proceedings (Accessed 2/5/03). [Available through http://www.hc-sc.gc.ca/, a website of Health Canada.]
- Schematic of the electrically heated cigarette smoking system first generation. Adapted from Roethig, H.J.; Oey, J.; Nelson, B.L.; Walk, R.-A., "Dose-response investigations of carboxyhemoglobin of adult smokers smoking conventional and electrically heated cigarettes". *Toxicological Sciences* 66 (1-S): 26-27; 2002. Poster presented at the 41st Annual Meeting of the Society of Toxicology, Nashville, TN, March 17-21, 2002. * Schematic of EHCSS
- Slade, J., "Innovative nicotine delivery devices from tobacco companies". In Nicotine and public health. Ferrence, Roberta; Slade, John; Room, Robin; Pope, Marilyn, eds. American Public Health Association; Washington, D.C. 2000.
- Slade, J.; Henningfield, J.E., "Tobacco product regulation: Context and Issues". The Food and Drug Law Journal 53 (Supplement): 43-74; 1998. Report (Accessed 2/5/03). [Available through the Food and Drug Law Journal website, http://www.fdli.org/.]
- Stratton, K.; Shetty, P.; Wallace, R.; Bondurant, S., eds. Clearing the smoke: Assassing the science base for tobacco harm reduction. National Institutes of Health, Institute of Medicine, Washington, D.C.: National Academies Press; 2001. <u>Book</u> (Accessed 2/5/03). [Available through the National Academies Press website, http://www.nap.edu/.]
- World Health Organization, "Advancing knowledge on regulating tobacco products".
 2000. Final report, Oslo, Norway, February 9-11, 2000. Report (Accessed 2/5/03).
 [Available through the World Health Organization website, http://www.who.int/en/.]

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This Methods Bibliography lists selected published or publicly presented scientific guidelines, standards and methods that relate to the assessment of the Electrically Heated Cigarette Smoking System (EHCSS) as of the date listed on the homepage.

The Methods Bibliography is not intended to be a comprehensive list of all published references available on the topic.

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References authored or co-authored by Philip Morris USA's or Philip Morris USA Affiliates' scientists are indicated with an asterisk (*). The references are listed in alphabetical order by first author.

The Methods bibliography is divided into 9 sections:

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I. Toxicological guidelines/approaches

- Adams, J.D.; O'Mara-Adams, K.J.; Hoffmann, D., "Toxic and carcinogenic agents in undiluted mainstream smoke and sidestream smoke of different types of cigarettes", Carcinogenesis 8 (5): 729-731; 1987. <u>Abstract</u> (Accessed 2/5/03).
- Borgerding, M.F.; Bodnar, J.A.; Chung, H.L.; Mangan, P.P.; Morrison, C.C.; Risner, C.H.; Rogers, J.C.; Simmons, D.F.; Uhrig, M.S.; Wendelboe, F.N.; Wingate, D.E.; Winkler, L.S., "Chemical and biological studies of a new cigarette that primarily heats tobacco. Part 1. Chemical composition of mainstream smoke". Food and Chemical Toxicology 36: 169-182; 1998. Abstract (Accessed 2/5/03).
- Carchman, R., "Identification of 'animal or organism-based' short-term tests which are available for the assessment of the potentially harmful properties of tobacco smoke". Report of Canada's expert committee on cigarette toxicity reduction. Conference Proceedings and Invited Papers, 1998. * Report (Accessed 2/5/03). [Available through http://www.hc-sc.gc.ca/, a website of Health Canada.]
- Carmines, E.L., "Evaluation of the potential effects of ingredients added to cigarettes. Part 1: Cigarette design, testing approach, and review of results". Food and Chemical Toxicology 40: 77-91; 2002. * Abstract (Accessed 2/5/03)
- Food and Drug Administration, Toxicological principles for the safety of food ingredients and color additives used in food. Draft Redbook II. Center for Food Safety and Applied Nutrition, 1993. Report (Accessed 2/5/03). [An updated version is available online through the Center for Food Safety & Applied Nutrition (CFSAN) website, http://vm.cfsan.fda.gov/. CFSAN is a branch of the Food and Drug administration.]
- Fowles, J.; Bates, M., "The chemical constituents in cigarettes and cigarette smoke: Priorities for harm reduction". A report to the New Zealand Ministry of Health. March 2000. Report (Accessed 2/5/03). [Available through http://www.ndp.govt.nz/, a website maintained by New Zealand's Inter-Agency Committee on Drugs (IACD).]
- Gori, G.B., Virtually Safe Cigarettes. Reviving an opportunity once tragically rejected. Amsterdam, The Netherlands: IOS Press; 2000.
- Haussmann, H.-J.; Rustemeier, K.; Elves, R.G., "The use of risk analysis in selecting cigarette smoke compounds for reduction". Poster presented at the Annual Meeting of the Society of Risk Analysis, Seattle, WA, December 2-5, 2001. * <u>Poster</u>.
- 9. International Agency for Research on Cancer. IARC Monographs on the evaluation of the carcinogenic risk of chemicals to humans: Tobacco Smoking, Volume 38. International Agency for Research on Cancer, World Health Organization, Lyon, France, 1986. Summary Information (Accessed 2/5/03), [Summary Information is available through The International Agency for Research on Cancer (IARC) website, http://www.iarc.fr/. IARC is a part of the World Health Organization.]
- Stratton, K.; Shetty, P.; Wallace, R.; Bondurant, S., eds. Clearing the smoke: Assessing the science base for tobacco harm reduction. National Institutes of Health, Institute of Medicine, Washington, D.C.: National Academies Press; 2001. <u>Book</u> (Accessed 2/5/03). [Available through the National Academies Press website, http://www.nap.edu/.]
- U.S. Environmental Protection agency, "Guidelines for the health risk assessment of chemical mixtures". Federal Register 51: 34014-24025; 1986.
- 12. United States Consumer Product Safety Commission, Practicability of Developing a Performance Standard to Reduce Cigarette Ignition Propensity. Washington, D.C.: United States Consumer Product Safety Commission; 1993. Report (Accessed 2/5/03). [Available through the US Consumer Product Safety Commission website, http://www.cpsc.gov/. The US Consumer Product Safety Commission is an independent agency of the US government.]
- United States Consumer Product Safety Commission, "Toxicity testing plan for low ignition-potential cigarettes". In: Lee, B.C.; Burns, D.M.; Gairola, C.G.; Harris, J.E.; Hoffmann, D.; Pillsbury, H.C., Jr.; Shopland, D.R., eds. *Toxicity Testing Plan*. Washington, D.C.: United States Consumer Product Safety Commission; Volume 5 Part 1, 1993.
- 14. Vorhees, D.J.; Herger-Bernays, W.; McClean, M.D., "Human Health Risk Associated with Cigarette Smoke: The link between smoke constituents and additives". Report

prepared for Mr. Turry Palothoa, menzie-oura & Associates, me., Chemisioro, Massachusetts; June 11, 1997.

 Vorhees, D.J.; Dodson, R.E., "Estimating risk to cigarette smokers from smoke constituents in proposed "testing and reporting of constituents of cigarette smoke" regulations". Report prepared for the Massachusetts Tobacco Control Program. Menzie-Cura & Associates, Inc., Chelmsford, Massachusetts; August 1999.

Methods Bibliography

[I. Toxicological guidelines/approaches] [II. Smoke chemistry] [III. Biomarkers] [IV. Bioassays] [V. Smoking topography] [VI. Clinical studies] [VII. Questionnaires for clinical studies] [VIII. Surveillance] [IX. General methods]

II. Smoke chemistry

.....

A. Mainstream smoke constituents

- Baker, R.R., "Smoke Chemistry". In: Davis, D.L.; Nielsen, M.T., eds. Tobacco Production, Chemistry and Technology. London: Blackwell Science Ltd.; 398-439, 1999.
- Borgerding, M.F.; Bodnar, J.A.; Chung, H.L.; Mangan, P.P.; Morrison, C.C.; Risner, C.H.; Rogers, J.C.; Simmons, D.F.; Uhrig, M.S.; Wendelboe, F.N.; Wingate, D.E.; Winkler, L.S., "Chemical and biological studies of a new cigarette that primarily heats tobacco. Part 1. Chemical composition of mainstream smoke". Food and Chemical Toxicology 36 (7): 169-182; 1998. Abstract (Accessed 2/5/03).
- Brunnemann, K.D.; Yu, L.; Hoffmann, D., "Chemical studies on tobacco smoke. 49. Gas chromatographic determination of hydrogen cyanide and cyanogen in tobacco smoke". Journal of Analytical Toxicology. 1: 38-42; 1977.
- Byrd, G.D.; Fowler, K.W.; Hicks, R.D.; Lovette, M.E.; Borgerding, M.F., "Isotope dilution gas chromatography-mass spectrometry in the determination of benzene, toluene, styrene and acrylonitrile in mainstream cigarette smoke". *Journal of Chromatography* 503: 359-368; 1990.
- Canada, "Tobacco Reporting Regulations SOR/2000-273". Tobacco Acta Section 42.1, registration June 26, 2000. <u>Regulation</u> (Accessed 2/5/03). [Available through https://www.hc-sc.gc.ca/, a website of Health Canada.]
- Diekmann, J.; Biefel, C.; Stabbert, R.; Rustemeier, K., "Analysis of unsymdimethylhydrazine in cigarette smoke". Program Booklet and Abstracts 55th Tobacco Science Research Conference, page 6; 2001. Poster presented at the 55th Tobacco Science Research Conference, Greensboro, NC, September 9-12, 2001. * Poster.
- Demetriou, D.; Schepers, G., "Determination of nIcotine and its metabolites in urine by HPLC after DETBA derivatization". Poster presented at Biomarkers for Tobacco Exposure: Application to Clinical and Epidemiological Studies, Minneapolis, MN, October 25-26, 2001. Poster presented at 8th Annual Meeting of Society for Research on Nicotine and Tobacco, Savannah, GA, February 20-23, 2002. * Poster.
- Federal Trade Commission, "Cigarettes: testing for tar and nicotine content". Federal Register 32: 11178; 1967.
- International Organization for Standardization, "Cigarettes Determination of nicotine content in smoke condensates - gas chromatographic method". International Organization for Standardization, ISO 10315: 1989.
- International Organization for Standardization, "Cigarettes Determination of total and nicotine-free dry particulate matter using a routine analytical smoking machine". International Organization for Standardization, 2nd edition, ISO 4387: 1991.
- International Organization for Standardization, "Cigarettes Determination of carbon monoxide in the vapour phase of cigarette smoke - NDIR method". International Organization for Standardization, 2nd edition, ISO 8454: 1995.
- International Organization for Standardization, "Cigarettes; determination of water in smoke condensates - Part 2: Karl Fischer method". International Organization for Standardization, ISO 10362-2: 1995.
- Massachusetts Department of Health, "Testing Methods". Tobacco Control Program 105 CMR 660.500, May 14, 1999. Regulation (Accessed 10/23/02). [Available through http://www.state.ma.us/, a website of the state of Massachusetts.]
- Nanni, E.J.; Lovette, M.E.; Hicks, R.D.; Fowler, K.W.; Borgerding, M.F.,
 "Separation and quantitation of phenolic compounds in mainstream cigarette
 smoke by capillary gas chromatography with mass spectrometry in the selectedion mode". *Journal of Chromatography* 505 (2): 365-374; 1990. <u>Abstract</u>
 (Accessed 2/5/03).
- 15 National Cancer Institute. The ETC cineratte test method for determining for

- nicotine, and carbon monoxide yields of U.S. cigarettes: Report of the NCI Expert Committee (Smoking and Tobacco Control Monograph 7; Publication No. NIH 96-2789). Washington, D.C.: U.S. Department of Health and Human Services; 1996.
- Rhoades, C.B.; White, R.T., "Mainstream smoke collection by electrostatic precipitation for acid dissolution in a microwave digestion system prior to trace metal determination". *Journal of AOAC International* 80; 1320-1331; 1997.
- Rustemeler, K.; Patskan, G.; Haussmann, H.-J., "The influence of a modified puffing regimen on the yields of smoke constituents from electrically heated and conventional research cigarettes". *The Toxicologist* 54 (1): 16; 2000. Poster presented at the 39th Annual Meeting of the Society of Toxicology, Philadelphia, PA, March 19-23, 2000. * <u>Poster</u>.
- Rustemeier, K.; Stabbert, R.; Haussmann, H.-J.; Roemer, E.; Carmínes, E.L., "Evaluation of the potential effects of ingredients added to cigarettes. Part 2: Chemical composition of mainstream smoke". Food and Chemical Toxicology 40: 93-104; 2002. * Abstract (Accessed 2/5/03).
- Stabbert, R.; Schaefer, K.-H.; Biefel, C.; Rustemeier, K., "Analysis of aromatic amines in cigarette smoke". Program Booklet and Abstracts 55th Tobacco Science Research Conference 69; 2001. Verbal presentation at the 55th Tobacco Science Research Conference, September 9-12, 2001, Greensboro, NC. *
- Wynder, E.L.; Hoffmann, D., Tobacco and tobacco smoke. New York, NY: Academic press, Inc.; 1967.

B. Sidestream smoke and ETS constituents

- Baker, R.R., "Smoke Chemistry". In: Davis, D.L.; Nielsen, M.T., eds. Tobacco Production, Chemistry and Technology. London: Blackwell Science Ltd.; 398-439, 1999.
- Gerstenberg, B.; Stinn, W.; Reininghaus, W., "Comparison of environmental tobacco smoke from an electrically heated and a conventional cigarette". Program Booklet and Abstracts 54th Tobacco Science Research Conference 19; 2000. Poster presented at the 54th Tobacco Science Research Conference, Nashville, TN, September 24-27, 2000. The Toxicologist 60 (1-S): 431; 2001. Poster presented at the 40th Annual Meeting of the Society of Toxicology, San Francisco, CA, March 25-29, 2001. * Poster.
- Jenkins, R.A.: Guerin, M.R.; Tomkins, B.A., The chemistry of environmental tobacco smoke: Composition and measurement. Eisenberg, M., series editor. Boca Raton: Lewis Publishers, Inc.; 2000. (Published by the Center for Indoor Air Research which was funded in part by Philip Morris USA Inc.)

Methods Bibliography

[I. Toxicological guidelines/approaches] [II. Smoke chemistry] [III. Biomarkers]
[IV. Bioassays] [V. Smoking topography] [VI. Clinical studies]
[VII. Questionnaires for clinical studies] [VIII. Surveillance] [IX. General methods]

III. Biomarkers

- Andersson, G.; Vala, E.K.; Curvall, M., "The influence of cigarette consumption and smoking machine yields of tar and nicotine on the nicotine uptake and oral disposal lesions in smokers". *Journal of Oral Pathology & Medicine* 26: 117-123; 1997. <u>Abstract</u> (Accessed 2/5/03).
- Benowitz, N.L., "Blomarkers of environmental tobacco smoke exposure". *Environmental Health Perspectives* 107 (Suppl. 2): 349-355; 1999. <u>Abstract</u> (Accessed 2/5/03).
- Benowitz, N. L., "The use of biologic fluid samples in assessing tobacco smoke consumption". NIDA Research Monograph, 48: 6-26; 1983. <u>Abstract</u> (Accessed 2/5/03).
- 4. Benowitz, N.L., "Biomarkers of environmental tobacco smoke exposure". In National Cancer Institute, The FTC cigarette test method for determining tar, nicotine, and carbon monoxide yields of U.S. cigarettes: Report of the NCI Expert Committee (Smoking and Tobacco Control Monograph 7; Publication No. NIH 96--2789). Washington, D.C.: U.S. Department of Health and Human Services; 1996.
- Benowitz, N.L.; Jacob, P. 3rd; Fong, I.; Gupta, S., "Nicotine metabolic profile in man: comparison of cigarette smoking and transdermal nicotine". *Journal of Pharmacology* and Experimental Therapeutics 268 (1): 296-303; 1994. <u>Abstract</u> (Accessed 2/5/03).
- Benowitz, N.L.; Jacob, P. 3rd, "Trans-3'-hydroxycotinine: disposition kinetics, effects and plasma levels during cigarette smoking". British Journal of Clinical Pharmacology 51 (1): 53-59; 2001. Abstract (Accessed 2/5/03).
- Boström, C.-E.; Gerde, P.; Hanberg, A.; Jernström, B.; Johansson, C.; Kyrklund, T.; Rannug, A.; Törnqvist, M.; Victorin, K.; Westerholm, R., "Cancer risk assessment, indicators, and guidelines for polycyclic aromatic hydrocarbons in the ambient air". Environmental Health Perspectives 110 (Suppl 3): 451-488; 2002. Abstract (Accessed 2/5/03).
- Boswell, C.; Curvali, M.; Elswick, R.K., Jr.; Leyden, D., "Modelling nicotine intake in smokers and snuff users using biological fluid nicotine metabolites". *Biomarkers* 5 (5): 341-354; 2000. *
- Branner, B.; Kutzer, C.; Zwickenpflug, W.; Scherer, G.; Heller, W.D.; Richter, E.,
 "Haemoglobin adducts from aromatic amines and tobacco-specific nitrosamines in
 pregnant smoking and non-smoking women". Blomarkers 3 (1): 35-47; 1998.
- Bryant, M.S.; Skipper, P.L.; Wishnok, J.S.; Stillwell, W.G.; Glogowski, J.A., Jr.; Tannenbaum, S.R., "Determination of haemoglobin adducts of aromatic amines by gas chromatography-mass spectrometry". In: Seifert, B.; van de Wiel, H.J.; Dodet, B.; O'Neill, I.K., eds. Environmental carcinogens methods of analysis and exposure measurement. Volume 12 - Indoor air. IARC Scientific Publications No. 109, International Agency for Research on Cancer, Lyon, France, 281-292, 1993.
- Byrd, G.D.; Chang, K.M.; Greene, J.M.; deBethizy, J.D., "Evidence for urinary excretion of glucuronide conjugates of nicotine, cofinine, and trans-3'-hydroxycotinine in smokers". *Drug Metabolism & Disposition* 20 (2): 192-197; 1992. <u>Abstract</u> (Accessed 2/5/03).
- Caldwell, W.S.; Greene, J.M.; Byrd, G.D.; Chang, K.M.; Uhrig, M.S.; deBethizy, J.D.; Crooks, P.A.; Bhatti, B.S.; Riggs, R.M., "Characterization of the glucuronide conjugate of cotinine: a previously unidentified major metabolite of nicotine in smokers' urine". Chemical Research in Toxicology 5 (2): 280-285; 1992. Abstract (Accessed 2/5/03).
- Castleden, C.M.; Cole, P.V., "Variations in carboxyhaemoglobin levels in smokers". Brltish Medical Journal 4 (5947): 736-738: 1974.
- Committee on Biological Markers of the National Research Council., "Biological markers in environmental health research". Environmental Health Perspectives, 74, 3-9, 1987.
- Demetriou, D.; Schepers, G., "Determination of nicotine and its metabolites in urine by HPLC after DETBA derivatization". Poster presented at Biomarkers for Tobacco Exposure: Application to Clinical and Epidemiological Studies, Minneapolis, MN, October 25-26, 2001. Poster presented at 8th Annual Meeting of Society for Research on Nicotine and Tobacco, Savannah, GA, February 20-23, 2002. * Poster.

- Ford, E.S.; Giles, W.H., "Serum C-reactive protein and self-reported stroke: findings from the Third National Health and Nutrition Examination Survey". Arteriosclerosis Thrombosis & Vascular Biology 20 (4): 1052-1056; 2000. Abstract (Accessed 2/5/03).
- Gorrod, J.W.; Jacob, P., Analytical determination of nicotine and related compounds and their metabolites, Amsterdam: Elsevier Science: 1999.
- Hammond, S.K.; Coghlin, J.; Gann, P.H.; Paul, M.; Taghizadeh, K.; Skipper, P.L.; Tannenbaum, S.R., "Relationship between environmental tobacco smoke exposure and carcinogen-hemoglobin adduct levels in nonsmokers". *Journal of the National Cancer Institute* 85: 474-478; 1993. <u>Abstract</u> (Accessed 2/5/03).
- 19. Health Effects Institute, "1,3-Butadiene: Cancer, mutations, and adducts", HEI Report Number 92. Cambridge MA: Health Effects Institute, 2000. Report (Accessed 2/5/03). [The report is available through The Health Effects Institute (HEI) website, http://www.healtheffects.org/. The HEI is an independent non-profit organization supported jointly by the U.S. Environmental Protection Agency (EPA) and industry.]
- Hecht, S.S.; Carmella, S.G.; Chen, M.; Dor Koch, J.F.; Miller, A.T.; Murphy, S.E.; Jensen, J.A.; Zimmerman, C.L., "Quantitation of urinary metabolites of a tobacco-specific lung carcinogen after smoking cessation". *Cancer Research* 59 (3): 590-596; 1999. Abstract (Accessed 2/5/03).
- Houeto, P.; Hoffman, J.R.; Got, P.; Dang, V.B.; Baud, F.J., "Acetonitrile as a possible marker of current cigarette smoking". *Human & Experimental Toxicology* 16 (11): 658-661; 1997. Abstract (Accessed 2/5/03).
- Jacob, P. 3rd; Yu, L.; Shulgin, A.T.; Benowitz, N.L., "Minor tobacco alkaloids as biomarkers for tobacco use: comparison of users of cigarettes, smokeless tobacco, cigars, and pipes". *American Journal of Public Health* 89 (5): 731-736; 1999. <u>Abstract</u> (Accessed 2/5/03).
- Jordan, A.; Hansel, A.; Hotzinger, R.; Lindinger, W., "Acetonitrile and benzene in the breath of smokers and non-smokers investigated by proton transfer reaction mass spectrometry (PTR-MS)". *International Journal of Mass Spectrometry and Ion Processes* 148 (1-2): L1-L3; 1995.
- 24. Kinser, R.D.; Carchman, R.A.; Leyden, D.E.; Sanders, E.B.; Stabbert, R.; Tricker, A.R.; von Holt, K.; Walk, R.A., "Selection of biomarkers of exposure for a population study of U.S. adult smokers to cigarette smoke". *Toxicology* 164: 41; 2001. Poster presented at the 9th International Congress of Toxicology, July 8-12, 2001, Brisbane, Australia, and at Biomarkers for Tobacco Exposure: Application to Clinical and Epidemiological Studies, Minneapolis, MN, October 25-26, 2001. * Poster.
- Kinser, R.D.; Oey, J., "Examples of systemic validation for biomarkers of cigarette smoke exposure". Poster presented at Biomarkers for Tobacco Exposure: Application to Clinical and Epidemiological Studies, Minneapolis, MN, October 25-26, 2001. * Link to poster. Poster.
- Kinser, R.D.; Nelson, B.; Roethig, H.-J.; Walk, R.-A.; Tricker, A.R.; Leyden, D.E., "Use
 of nicotine and NNK metabolites to assess exposure to cigarette smoke constituents;
 Pilot study results". Poster presented at 8th Annual Meeting of Society for Research on
 Nicotine and Tobacco, Savannah, GA, February 20-23, 2002. * Poster.
- Kinser, R.D.; Nelson, B.L.; Roethig, H.J.; Walk, R.-A.; Oey, J.; Tricker, A.R.; Leyden, D.E., "Assessment of human exposure to cigarette smoke constituents; Pilot study results for carbon monoxide". *The Toxicologist* 66, (1-S): 26, 2002. Poster presented at the 41st Society of Toxicology Annual Meeting, Nashville, TN, March 17-21, 2002. * Poster
- Klesges, L.M.; Klesges, R.C.; Cigrang, J.A., "Discrepancies between self-reported smoking and carboxyhemoglobin: an analysis of the second national health and nutrition survey". American Journal of Public Health 82: 1026-1029; 1992. Abstract (Accessed 2/5/03).
- Klimisch, H.J.; Meissner, K.; Wernicke, H., "Quantitative determination of carbon monoxide in blood by gas chromatography". Zeitschrift für Klinische Chemie und Klinische Biochemie 12: 535-538; 1974.
- Lindinger, W.; Hansel, A.; Jordan, A., "On-line monitoring of votatile organic compounds at pptv levels by means of Proton-Transfer-Reaction Mass Spectrometry (PTR-MS) Medical applications, food control and environmental research". International Journal of Mass Spectrometry and Ion Processes 173 (3): 191-241; 1998.
- Maclure, M.; Katz, R.B.; Byrant, M.S.; Skipper, P.L.; Tannenbaum, S., "Elevated blood levels of carcinogens in passive smokers". *American Journal of Public Health* 79 (10): 1381-1384; 1989. Abstract (Accessed 2/5/03).
- Meger, M.; Meger-Kossien, I.; Dietrich, M.; Tricker, A.R.; Scherer, G.; Adikofer, F., "Metabolites of 4-(N-methylnitrosamino)-1-(3-pyridyl)-1-butanone in urine of smokers". European Journal of Cancer Prevention 5 (Suppl 1): 121-124; 1996. *
- Meger, M.; Meger-Kossien, I.; Riedel, K.; Scherer, G., "Biomonitoring of environmental tobacco smoke (ETS)-related exposure to 4-(methylnitrosamino)-1-(3-pyridyl)-1butanone (NNK)". Biomarkers 5 (1): 33-45; 2000.
- 34. Michaelis, H.C.; Clemens, C.; Kijewski, H.; Neurath, H.; Eggert, A., "Acetonitrile serum

concentrations and cyanide blood levels in a case of sulcidal oral acetonitrile ingestion". *Journal of Toxicology - Clinical Toxicology* 29 (4): 447-458; 1991. <u>Abstract</u> (Accessed 2/5/03).

- Middleton, E.T.; Morice, A.H., "Breath carbon monoxide as an indication of smoking habit". Chest 117: 758-763; 2000. Abstract (Accessed 2/5/03).
- Mooney, L.A.; Santella, R.M.; Covey, L.; Jeffrey, A.M.; Bigbee, W.; Randall, M.C.; Cooper, T.B.; Ottman, R.; Tsai, W.Y.; Wazneh, L., "Decline of DNA damage and other biomarkers in peripheral blood following smoking cessation". *Cancer Epidemiology Biomarkers & Prevention* 4: 627-634; 1995. Abstract (Accessed 2/5/03).
- Patrianakos, C.; Hoffmann, D., "Chemical studies on tobacco smoke. LXIV. On the analysis of aromatic amines in cigarette smoke". *Journal of Analytical Toxicology* 3: 150-154; 1979.
- Prazeller, P.; Karl, T.; Jordan, A.; Holzinger, R.; Hansel, A.; Lindinger, W.,
 "Quantification of passive smoking using proton-transfer-reaction mass spectrometry".
 International Journal of Mass Spectrometry and Ion Processes 178 (3): L1-L4; 1998.
- Rahman, I.; MacNee, W., "Role of oxidants/antioxidants in smoking-induced lung diseases". Free Radical Biology and Medicine 21 (5): 669-681; 1996. <u>Abstract</u> (Accessed 2/5/03).
- Reilly, M.; Delanty, N.; Lawson, J.A.; FitzGerald, G.A., "Modulation of oxidant stress in vivo in chronic cigarette smokers". *Circulation* 94 (1): 19-25; 1996. <u>Abstract</u> (Accessed 2/5/03).
- Roethig, H.J.; Oey, J.; Nelson, B.N.; Walk, R.A., "Dose-response Investigations of carboxyhemoglobin of adult smokers smoking conventional and electrically heated cigarettes". The Toxicologist 66, (1-S): 26, 2002. Poster presented at the 41st Annual Meeting of the Society of Toxicology, Nashville, TN, March 17-21, 2002. * Poster.
- Roethig, H.J.; von Holt, K.; Kuhl, P.; McKinney, W.; Zhang, M.; Walk, R.-A., "Biomarkers of potential harm in smokers". Poster presented at Biomarkers for Tobacco Exposure: Application to Clinical and Epidemiological Studies, Minneapolis, MN, October 25-26, 2001. * Poster.

District

- Rustemeier, K.; Demetriou, D.; Schepers, G.; Voncken, P., "High-performance liquid chromatographic determination of nicotine and its urinary metabolites via their 1,3diethyl-2-thiobarbituric acid derivatives". *Journal of Chromatography* 613: 95-103; 1993. *
- Schepers, G.; Demetriou, D.; Stabbert, R.; Diehl, B., "Isolation and identification of nicotine phase 2 metabolites from smoker's urine". Poster presented at the Second Annual Conference of the Society for Research on Nicotine and Tobacco, Washington, D.C., March 15-17, 1996. * Poster.
- Schepers, G.; Demetriou, D.; Stabbert, R.; Diehl, B.; Seeman, J.i., "5'-hydroxycotinine-N-oxide, a new nicotine metabolite isolated from rat urine". *Xenobiotica* 29: 793-801; 1999. * Abstract (Accessed 2/5/03).
- Schepers, G.; Rustemeier, K.; Walk, R.-A.; Hackenberg, U., "Metabolism of S-nicotine in noninduced and Aroctor-induced rats". European Journal Drug Metabolism Pharmacokinetics 18 (2): 187-197; 1993. * Abstract (Accessed 2/5/03).
- Seaton, M.J.; Vesell, E.S.; Luo, H.; Hawes, E.M., "Identification of radiolabeled metabolites of nicotine in rat bile. Synthesis of S-(-)-nicotine N-glucuronide and direct separation of nicotine-derived conjugates using high-performance liquid chromatography". *Journal of Chromatography* 621 (1): 49-53; 1993. <u>Abstract</u> (Accessed 2/5/03).
- Weinreich, R.; Ritzl, F.; Feinendegen, L.E.; Schnippering, H.G.; Stocklin, G., "Fixation, retention and exhalation of carrier-free 11C-labeled carbon monoxide by man".
 Radiation & Environmental Biophysics 12 (4): 271-280; 1975. Abstract (Accessed 2/5/03).

Methods Bibliography

[I. Toxicological guidelines/approaches] [II. Smoke chemistry] [III. Biomarkers]
[IV. Bioassays] [V. Smoking topography] [VI. Clinical studies]
[VII. Questionnaires for clinical studies] [VIII. Surveillance] [IX. General methods]

IV. Bioassavs

1 2...

- Abramsson-Zetterberg, L.; Grawe, J.; Zetterberg, G., "The micronucleus test in rat erythrocytes from bone marrow, spleen and peripheral blood: the response to low doses of ionizing radiation, cyclophosphamide and vincristine determined by flow cytometry". *Mutation Research* 423 (1-2): 113-124; 1999. Abstract (Accessed 2/5/03).
- Ames, B.N.; McCann, J.; Yamasaki, E., "Methods for detecting carcinogens and mutagens with the Salmonellalmammalian-microsome mutagenicity test". Mutation Research 31; 347-364; 1975.
- Asanami, S.; Shimono, K.; Sawamoto, O.; Kurisu, K.; Uejima, M., "The suitability of rat peripheral blood in subchronic studies for the micronucleus assay". *Mutation Research* 347 (2): 73-78; 2002. <u>Abstract</u> (Accessed 2/5/03).
- Balansky, R.M.; Blagoeva, P.M.; Mircheva, Z.I., "The mutagenic and clastogenic activity of tobacco smoke". Mutation Research 208 (3-4): 237-241; 1988. <u>Abstract</u> (Accessed 2/5/03).
- Bombick, D.W.; Ayres, P.H.; Putnam, K.P.; Bombick, B.R.; Doolittle, D.J., "Chemical and biological studies of a new cigarette that primarily heats tobacco. Part 3. In vitro Toxicity of Whole Smoke". Food and Chemical Toxicology 36: 191-197; 1998. Abstract (Accessed 2/5/03).
- Bombick, B.R.; Murli, H.; Avalos, J.T.; Bombick, D.W.; Morgan, W.T.; Putnam, K.P.; Doolittle, D.J., "Chemical and biological studies of a new cigarette that primarily heats tobacco. Part 2. In vitro toxicology of mainstream smoke condensate". Food and Chemical Toxicology 36: 183-190; 1998. Abstract (Accessed 2/5/03).
- Borenfreund, E.; Puerner, J.A., "Toxicity determined in vitro by morphological alterations and neutral red absorption". *Toxicology Letters* 24: 119-124; 1985.
 Abstract (Accessed 2/5/03).
- Borenfreund, E.; Puerner, J.A., "A simple quantitative procedure using monolayer cultures for cytotoxicity assay (HTD/NR 90)". *Journal of Tissue Culture Method* 9 (1): 7-9: 1984.
- Borenfreund, E.; Babich, H.; Martin-Alguacii, N., "Comparisons of two in vitro cytotoxicity assays - the neutral red (NR) and tetrazolium MTT tests". Toxicology in Vitro 2: 1-6; 1988.
- Brown, B.G.; Lee, C.K.; Bombick, B.R.; Ayres, P.H.; Mosberg, A.T.; Doolittle, D.J., "Comparative study of DNA adduct formation in mice following inhalation of smoke from cigarettes that burn or primarily heat tobacco". *Environmental & Molecular Mutagenesis* 29 (3): 303-311; 1997. Abstract (Accessed 2/5/03).
- Chepiga, T.A.; Morton, M.J.; Murphy, P.A.; Avalos, J.T.; Bombick, B.R.; Doolittle, D.J.; Borgerding, M.F.; Swauger, J.E., "A comparison of the mainstream smoke chemistry and mutagenicity of a representative sample of the US cigarette market with two Kentucky reference cigarettes (K1R4F and K1R5F)". Food and Chemical Toxicology 38: 949-962; 2000. Abstract (Accessed 2/5/03).
- Clive, D.; Flamm, W.G.; Machesko, M.R.; Bernheim, N.J., "A mutational assay system using the thymidine kinase locus in mouse lymphoma cells". *Mutation Research* 16 (7): 77-87; 1972.
- Coggins, C.R.; Ayres, P.H.; Mosberg, A.T.; Sagartz, J.W.; Burger, G.T.; Hayes, A.W., "Ninety-day inhalation study in rats, comparing smoke from cigarettes that heat tobacco with those that burn tobacco". Fundamental and Applied Toxicology 13; 460-483; 1989.
- Cole, J.; Muriel, W.J.; Bridges, B.A., "The mutagenicity of sodium fluoride to L5178Y [wild-type and TK+/- (3.7.2c)] mouse lymphoma cells". *Mutagenesis* 1 (2): 157-167; 1986. Abstract (Accessed 2/5/03).
- DeMarini, D.M., "Genotoxicity of tobacco smoke and tobacco smoke condensates". *Mutation Research* 114: 59-89: 1983.
- Draper, R.; Tewes, F.; Haussmann, H.-J., "A comprehensive standardization protocol for the routine biochemical characterization of a rat liver metabolic promutagen activation system used for in vitro mutagenicity assays". Mutagenesis 5: 619: 1990. *
- 17 Garriott M.L. Rainnu I.D. Kindia D.E. Dartan J.W. Sahuriar I.S. "The in vive ref.

- micronucleus test: integration with a 14-day study". Mutation Research 342 (1-2); 71-76: 1995. Abstract (Accessed 2/5/03).
- Gaworski, C.L.; Dozier, M.N.; Gerhart, J.M.; Rajendran, N.; Brennecke, L.H.; Aranyi, C.; Heck, J.D., "13-week inhalation toxicity study of menthol cigarette smoke". Food and Chemical Toxicology 35 (7): 683-692; 1997. Abstract (Accessed 2/5/03).
- Haussmann, H.-J.; Anskeit, E.; Becker, D.; Kuhl, P.; Stinn, W.; Teredesai, A.; Voncken, P.; Walk, R.-A., "Comparison of fresh and room-aged cigarette sidestream smoke in a subchronic inhalation study on rats". *Toxicological Sciences* 41: 100-116; 1998. * Abstract (Accessed 2/5/03).
- Haussmann, H.-J.; Gerstenberg, B.; Goecke, W.; Kuhl, P.; Schepers, G.; Stabbert, R.; Stinn, W.; Teredesai, A.; Tewes, F.; Anskelt, E.; Terpstra, P., "12-Month inhalation study on room-aged cigarette sidestream smoke in rats". *Inhalation Toxicology* 10 (7): 663-697: 1998. *
- 21. Hayashi, M.; Kodama, Y.; Awogi, T.; Suzuki, T.; Asita, A.O.; Sofuni, T., "The micronucleus assay using peripheral blood reticulocytes from mitomycin C- and cyclophosphamide-treated rats". *Mutation Research* 278 (2-3): 209-213; 1992. Abstract (Accessed 2/5/03).
- 22. International Conference on Harmonisation, "International conference on harmonisation of technical requirements for registration of pharmaceuticals for human use: Guidance on specific aspects of regulatory genotoxicity tests for "pharmaceuticals". International Federation of Pharmaceutical Manufacturers Associations (IFPMA), 38, 1995. Published version (Accessed 2/5/03). [A published version is available through the Food and Drug Administration website, http://www.fda.gov/.
- 23. INVITTOX ERGATT/FRAME, "The FRAME modified neutral red uptake cytotoxicity test", INVITTOX Protocol no. 3a. INVITTOX: The ERGATT/FRAME/ECVAM Data Bank of In Vitro Techniques in Toxicology, Nottingham, 1990. Protocols (Available after free registration, accessed 10/23/02). [INVITTOX protocols are available through the Scientific Information Service website, http://ecvam-sls.jrc.it/.]
- Kaegler, M.; Teredesal, A.; Vanscheeuwijck, P.; Terpstra, P.; Gerstenberg, B.,
 "Comparison of two exposure regimens in rat subchronic inhalation studies with
 cligarette smoke". The Toxicologist 54 (1): 17; 2000. Poster presented at the 39th
 Annual Meeting of the Society of Toxicology, Philadelphia, PA, March 19-23, 2000. *
 Poster.
- Kaegler, M.; Anskeit, E.; Teredesai, A.; Vanscheeuwijck, P.; Terpstra, P., "Suitability of different exposure regimens in subchronic inhalation studies with cigarette smoke". The Toxicologist 60: 431; 2001. Poster presented at the 40th Annual Meeting of the Society of Toxicology, San Francisco, CA, March 25-29, 2001. * Poster.
- Maron, D.M.; Ames, B.N., "Revised methods for the Salmonella mutagenicity test". *Mutation Research* 113: 173-215; 1983. Abstract (Accessed 2/5/03).
- Organization for Economic Co-operation and Development, "OECD Test Guideline 413, subchronic inhalation toxicity: 90-day study". OECD Guidelines for testing of chemicals, May 12, 1981.
- Organization for Economic Co-operation and Development, "OECD Test Guideline 471, bacterial reverse mutation test". OECD Guidelines for testing of chemicals, July 1, 1997.
- Organization for Economic Co-operation and Development, "OECD Test Guideline 474, mammalian erythrocyte micronucleus test". OECD Guidelines for testing of chemicals, July 1, 1997.
- Roemer, E.; Meisgen, T.J.; Tewes, F.J.; Solana, R.P., "Discrimination of cigarette mainstream smoke condensates with the Salmonella reverse mutation assay". The Toxicologist 42 (1-S): 295; 1998. Poster presented at the 37th Annual Meeting of the Society of Toxicology, Seattle, WA, March 1-5, 1998. * Poster.
- Roemer, E.; Teredesai, A.; Terpstra, P.; Vanscheeuwijck, P.M.; Haussmann, H.-J.,
 "The discriminative power of rat inhalation studies investigating the irritative property of
 inhalants". Poster presented at the Validity of Animal Models of Human Respiratory
 Disease Conference, Santa Fe, NM, September 30 October 2, 1998. * Poster.
- Roemer, E.; Tewes, F.J.; Meisgen, T.J.; Veltel, D.J.; Carmines, E.L., "Evaluation of the
 potential effects of ingredients added to cigarettes. Part 3: In vitro genotoxicity and
 cytotoxicity". Food and Chemical Toxicology 40: 105-111; 2002. * <u>Abstract</u> (Accessed
 2/5/03).
- Romagna, F.; Staniforth, C.D., "The automated bone marrow micronucleus test". *Mutation Research* 213 (1): 91-104; 1989. <u>Abstract</u> (Accessed 2/5/03).
- Schlegel, R.; MacGregor, J.T., "The persistence of micronucleated erythracytes in the peripheral circulation of normal and splenectomized Fischer 344 rats: implications for cytogenetic screening". *Mutation Research* 127 (2): 169-174; 1984. <u>Abstract</u> (Accessed 2/5/03).
- Schramke, H.; Tewes, F.J.; Roemer, E., "Using the mouse lymphoma TK assay to compare the mutagenicity of mainstream smoke condensate from research cigarettes".

...

- The Toxicologist 66 (1-S): 71; 2002. Poster presented at the 41st Annual Meeting of the Society of Toxicology, Nashville, TN, March 17-21, 2002. * Poster.
- Steele, R.H.; Payne, V.M.; Fulp, C.W.; Rees, D.C.; Lee, C.K.; Doolittle, D.J., "A comparison of the mutagenicity of mainstream cigarette smoke condensates from a representative sample of the U.S. cigarette market with a Kentucky reference cigarette (K1R4F)". Mutation Research 342 (3/4): 179-190; 1995. Abstract (Accessed 2/5/03).
- Tewes, F.J.; Meisgen, T.J.; Gomm, W.A.; Roemer, E.; Carchman, R.A., "Cigarette parameters that influence the mutagenicity of mainstream smoke condensate". *The Toxicologist* 48 (1-S): 125; 1999. Poster presented at 38th Annual Meeting of Society of Toxicology, New Orleans, LA, March 14-18, 1999. * <u>Poster</u>.
- Torous, D.K.; Dertinger, S.D.; Hall, N.E.; Tometsko, C.R., "Enumeration of micronucleated reticulocytes in rat peripheral blood: a flow cytometric study". *Mutation Research* 465 (1-2): 91-99; 2000. <u>Abstract</u> (Accessed 2/5/03).
- Vanscheeuwijck, P.; van Miert, E.; Meurrens, K.; Terpstra, P.M., "The micronucleus assay for the determination of cigarette mainstream smoke activity in bone marrow and peripheral blood of rats". *The Toxicologist* 60: 431; 2001. Poster presented at the 40th Annual Meeting of the Society of Toxicology, San Francisco, CA, March 25-29, 2001. * Poster.
- Vanscheeuwijck, P.M.; Teredesai, A.; Terpstra, P.M.; Verbeeck, J.; Kuhl, P.; Gerstenberg, B.; Gebel, S.; Carmines, E.L., "Evaluation of the potential effects of ingredients added to cigarettes. Part 4: subchronic inhalation toxicity". Food and Chemical Toxicology 40: 113-131; 2002. * <u>Abstract</u> (Accessed 2/5/03).
- Yoshida, D.; Matsumota, T., "Changes in mutagenicity of protein pyrolyzates by reaction with nitrite". Mutation Research 58: 35-40; 1978. Abstract (Accessed 2/5/03).

Methods Bibliography

[I. Toxicological guidelines/approaches] [II. Smoke chemistry] [III. Biomarkers] [IV. Bioassays] [V. Smoking topography] [VI. Clinical studies] [VII. Questionnaires for clinical studies] [VIII. Surveillance] [IX. General methods]

V. Smoking topography

...

- Baker, R.R., "The development and significance of standards for smoking-machine methodology". Beiträge zur Tabakforschung International 20 (1): 23-41; 2002.
- Benowitz, N.L.; Hall, S.M.; Herning, R.L.; Jacob, P. 3rd; Jones, R.T.; Osman, A.L., "Smokers of low-yield cigarettes do not consume less nicotine". N. Engl. J. Med. 309 (3): 139-142; 1983. Abstract (Accessed 2/5/03).
- United States Consumer Product Safety Commission, "Toxicity testing plan for low ignition-potential cigarettes". In: Lee, B.C.; Burns, D.M.; Gairola, C.G.; Harris, J.E.; Hoffmann, D.; Pillsbury, H.C., Jr.; Shopland, D.R., eds. Toxicity Testing Plan Washington, D.C.: United States Consumer Product Safety Commission; Volume 5 Part 1, 1993.
- Walk, R.-A.; Carter, W.H.; Carchman, R.A.; Gear, J.C.; Gomm, W.; Gennings, C.; Kinser, R.D.; Leyden, D.E.; Nelson, B.L.; Tricker, A.R.; von Holt, K., "Design for a population study of exposure of U.S. adult smokers to cigarette smoke". *Toxicology* 164: 41; 2001. Poster presented at the 9th International Congress of Toxicology, July 8-12, 2001, Brisbane, Australia, and at Biomarkers for Tobacco Exposure: Application to Clinical and Epidemiological Studies, Minneapolls, MN, October 25-26, 2001. *

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Methods Bibliography

[I. <u>Toxicological guidelines/approaches</u>] [II. <u>Smoke chemistry</u>] [III. <u>Biomarkers</u>] [IV. <u>Bioassays</u>] [V. <u>Smoking topography</u>] [VI. <u>Clinical studies</u>] [VII. <u>Questionnaires for clinical studies</u>] [VIII. <u>Surveillance</u>] [IX. <u>General methods</u>]

VI. Clinical studies

- Andersson, G.; Vala, E.K.; Curvall, M., "The influence of cigarette consumption and smoking machine yields of tar and nicotine on the nicotine uptake and oral mucosal lesions in smokers". *Journal of Oral Pathology & Medicine* 26 (3): 117-123; 1997.
 Abstract (Accessed 2/5/03).
- Association of Clinical Research Professionals, Federal regulations and guidelines reference manual. Washington, D.C.: Association of Clinical Research Professionals; 2001.
- Byrd, G.D.; Davis, R.A.; Caldwell, W.S.; Robinson, J.H.; deBethizy, J.D., "A further study of FTC yield and nicotine absorption in smokers". *Psychopharmacology (Berl)* 139: 291-299; 1998. <u>Abstract</u> (Accessed 2/5/03).
- Byrd, G.D.; Robinson, J.H.; Caldwell, W.S.; deBethizy, J.D., "Comparison of measured and FTC-predicted nicotine uptake in smokers". *Psychopharmacology (Berl)* 122: 95-103; 1995. Abstract (Accessed 2/5/03).
- Djordjevic, M.V.; Stellman, S.D.; Zang, E., "Doses of nicotine and lung carcinogens delivered to cigarette smokers". *Journal of the National Cancer Institute* 92: 106-111; 2000. Abstract (Accessed 2/5/03).

cessed 10

- Jarvis, M.J.; Boreham, R.; Primatesta, P.; Feyerabend, C.; Bryant, A., "Nicotine yield from machine-smoked cigarettes and nicotine intakes in smokers: evidence from a representative population survey". *Journal of the National Cancer Institute* 93: 134-138; 2001. Abstract (Accessed 2/5/03).
- Kinser, R.D.; Carchman, R.A.; Leyden, D.E.; Sanders, E.B.; Stabbert, R.; Tricker, A.R.; von Holt, K.; Walk, R.A., "Selection of biomarkers of exposure for a population study of U.S. adult smokers to cigarette smoke". *Toxicology* 164: 41; 2001. Poster presented at the 9th International Congress of Toxicology, July 8-12, 2001, Brisbane, Australia, and at Biomarkers for Tobacco Exposure: Application to Clinical and Epidemiological Studies, Minneapolis, MN, October 25-26, 2001. * Poster.
- Kinser, R.D.; Nelson, B.; Roethig, H.-J.; Walk, R.-A.; Tricker, A.R.; Leyden, D.E., "Use
 of nicotine and NNK metabolites to assess exposure to cigarette smake constituents:
 Pilot study results". Poster presented at 8th Annual Meeting of Society for Research on
 Nicotine and Tobacco, Savannah, GA, February 20-23, 2002. * Poster.
- Kinser, R.D.; Nelson, B.L.; Roethig, H.J.; Walk, R.-A.; Oey, J.; Tricker, A.R., Leyden, D.E., "Assessment of human exposure to cigarette smoke constituents; Pilot study results for carbon monoxide". *The Toxicologist* 66 (1-S): 26, 2002. Poster presented at the 41st Annual Meeting of the Society of Toxicology, Nashville, TN, March 17-21, 2002. * Poster.
- Kinser, R.D.; Oey, J., "Examples of systematic validation for biomarkers of cigarette smoke exposure". Poster presented at Biomarkers for Tobacco Exposure: Application to Clinical and Epidemiological Studies, Minneapolls, MN, October 25-26, 2001. * Poster.
- Lau, R.; Zhang, M.; Nelson, B.; Adams, C.; Walk, R.A., "Assessment of environmental tobacco smoke (ETS) exposure among non-smokers and smokers using biomarkers and a questionnaire". Poster presented at Biomarkers for Tobacco Exposure: Application to Clinical and Epidemiological Studies, Minneapolis, MN, October 25-26, 2001. * Poster.
- National Cancer Institute, "Risks associated with smoking cigarettes with low machine-measured yields of tar and nicotine". Smoking and Tobacco Control Monograph No. 13. Bethesda, MD: U.S. Department of Health and Human Servicas, National Institutes of Health, National Cancer Institute, NIH Pub. No. 02-5074; 2001. Monograph (Accessed 2/5/03). [Available from the National Cancer Institute website, http://cancercontrol.cancer.gov/.]
- Roethig, H.J.; Oey, J.; Nelson, B.N.; Walk, R.-A., "Dose-response investigations of carboxyhemoglobin of adult smokers smoking conventional and electrically heated cigarettes". The Toxicologist 66 (1-S): 26, 2002. Poster presented at the 41st Annual Meeting of the Society of Toxicology, Nashville, TN, March 17-21, 2002. * Poster.
- 14. Roethig, H.J.; von Holt, K.; Kuhl, P.; McKinney, W.; Zhang, M.; Walk, R.-A.,

Tobacco Exposure: Application to Clinical and Epidemiological Studies, Minneapolis, MN, October 25-26, 2001. * Poster.

- Rosa, M.; Pacifici, R.; Altieri, I.; Pichini, S.; Ottaviani, G.; Zuccaro, P., "How the steady-state cotinine concentration in cigarette smokers is directly related to nicotine intake". Clinical Pharmacology and Therapeutics 52: 324-329; 1992. <u>Abstract</u> (Accessed 2/5/03).
- Stratton, K.; Shetty, P.; Wallace, R.; Bondurant, S., eds. Clearing the smoke: Assessing the science base for tobacco harm reduction. National Institutes of Health, Institute of Medicine, Washington, D.C.: National Academies Press; 2001. <u>Book</u> (Accessed 2/5/03). [Available through the National Academies Press website, http://www.nap.edu/.]
- 17. Walk, R.-A.; Carter, W.H.; Carchman, R.A.; Gear, J.C.; Gomm, W.; Gennings, C.; Kinser, R.D.; Leyden, D.E.; Nelson, B.L.; Tricker, A.R.; von Holt, K., "Design for a population study of exposure of U.S. adult smokers to cigarette smoke". *Toxicology* 164: 41; 2001. Poster presented at the 9th International Congress of Toxicology, July 8-12, 2001, Brisbane, Australia, and at Biomarkers for Tobacco Exposure: Application to Clinical and Epidemiological Studies, Minneapolis, MN, October 25-26, 2001. *Poster.

....

18. World Health Organization, "Human exposure assessment". Environmental Health Criteria, No. 214. World Health Organization Geneva, Switzerland; 2000. Report (Accessed 2/5/03). [Available through the International Programme on Chemical Safety (IPCS) website, http://www.inchem.org/. IPCS is a cooperative programme of the World Health Organization (WHO), the International Labour Organisation (ILO), and the United Nations Environment Programme (UNEP).]

Methods Bibliography

[I. <u>Toxicological guidelines/approaches</u>] [II. <u>Sm</u>oke chemistry] [III. <u>Biomarkers</u>] [IV. Bioassays] [V. <u>Smoking topography</u>] [VI. Clinical studies] [VII. Questionnaires for clinical studies] [VIII. Surveillance] [IX. General methods]

VII. Questionnaires for clinical studies

- Lau, R.; Zhang, M.; Nelson, B.; Adams, C.; Walk, R.-A., "Assessment of environmental tobacco smoke (ETS) exposure among non-smokers and smokers using biomarkers and a questionnaire". Poster presented at Biomarkers for Tobacco Exposure: Application to Clinical and Epidemiological Studies, Minneapolis, MN, October 25-26, 2001. * Poster.
- Walk, R.-A.; Carter, W.H.; Carchman, R.A.; Gear, J.C.; Gomm, W.; Gennings, C.; Kinser, R.D.; Leyden, D.E.; Nelson, B.L.; Tricker, A.R.; von Holt, K., "Design of a population study of exposure of U.S. adult smokers to cigarette smoke". *Toxicology* 164: 41; 2001. Poster presented at the 9th international Congress of Toxicology, July 8-12, 2001, Brisbane, Australia, and at Biomarkers for Tobacco Exposure: Application to Clinical and Epidemiological Studies, Minneapolis, MN, October 25-26, 2001. * Poster.

Methods Bibliography

[I. Toxicological guidelines/approaches] [II. Smoke chemistry] [III. Biomarkers]
[IV. Bioassays] [V. Smoking topography] [VI. Clinical studies]
[VII. Questionnaires for clinical studies] [VIII. Surveillance] [IX. General methods]

VIII. Surveillance

- National Cancer Institute, "Risks associated with smoking cigarettes with low machine-measured yields of tar and nicotine". Smoking and Tobacco Control Monograph No. 13. Bethesda, MD: U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute, NIH Pub. No. 02-5074; 2001. Monograph (Accessed 2/5/03). [Available from the National Cancer Institute website, http://cancercontrol.cancer.gov/.]
- Stratton, K.; Shetty, P.; Wallace, R.; Bondurant, S., eds. Clearing the smoke: Assessing the science base for tobacco harm reduction. National Institutes of Health, Institute of Medicine, Washington, D.C.: National Academies Press; 2001. <u>Book</u> (Accessed 2/5/03). [Available through the National Academies Press website, http://www.nap.edu/.]
- Lee, P.N., "Lung cancer and type of agarette smoked". Inhalation Toxicology 13 (11): 951-976; 2001. Abstract (Accessed 2/5/03).

Methods Bibliography

[]. Toxicological guidelines/approaches] [II. Smoke chemistry] [III. Biomarkers] [IV. Bioassays] [V. Smoking topography] [VI. Clinical studies]
[VII. Questionnaires for clinical studies] [VIII. Surveillance] [IX. General methods]

IX. General methods

- American Association for Laboratory Animal Science, "American Association for Laboratory Animal Science Policy on the humane care and use of laboratory animals". Laboratory Animal Science 41: 91: 1991.
- 2. Diana, J.N.; Vaught, A. "Research cigarettes". The University of Kentucky Printing Services, Lexington, KY. 1990.
- 3. Dunnett, C.W., "A multiple comparison procedure for comparing several treatments with a control". Journal of the American Statistical Association 50: 1096-1121: 1955.
- Food and Drug Administration, "International conference on harmonisation; good clinical practice: consolidated guideline; notice of availability". Federal Register 62: 25691-25709; 1997.
- Food and Drug Administration; Center for Drug Evaluation and Research (CDER), "Guidance for industry. Bioanalytical method validation". Report issued May 2001. Report (Accessed 2/5/03. [Available through the Food and Drug Administration website http://www.fda.gov.]
- International Agency for Research on Cancer, "IARC Monographs on the evaluation of the carcinogenic risk of chemicals to humans". A series of monographs published by IARC starting in 1972. <u>List of monographs</u> (Accessed 2/5/03). [A listing of monographs available online can be seen through the IARC website. http://www.iarc.fr/.]
- 7. International Organization for Standardization, "Cigarettes Routine analytical cigarette-smoking machine-Definitions and standard conditions", 3rd edition, ISO 3308:
- 8. International Organization for Standardization, "Tobacco and tobacco products -Atmosphere for conditioning and testing". International Organization for Standardization, 3rd edition, ISO 3402: 1991.
- 9. Mann, H.B.; Whitney, D.K., "On a test of whether one of two random variables is stochastically larger than the other". Annals of Mathematical Statistics 18: 50-60; 1947.
- 10. Organization for Economic Co-operation and Development, "GLP, Consensus document: The OECD principles of good laboratory practice", 1992,
- 11. Reininghaus, W.; Hackenberg, U., "Anlage zur Langzeit-inhalation mit Zigarettenrauch für kleine Labortiere". Medizinische Technik 97: 5-6; 1977.
- 12. Sachs, L., Applied Statistics. New York: Springer Verlag; 1982.
- 13. Stratton, K.; Shetty, P.; Wallace, R.; Bondurant, S., eds. Clearing the smoke: Assessing the science base for tobacco harm reduction. National Institutes of Health, Institute of Medicine, Washington, D.C.: National Academies Press; 2001. Book (Accessed 2/5/03). [Available through the National Academies Press website, http://www.nap.edu/.]

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